Paracervical Block for Pain Control in First-Trimester Surgical Abortion

A Randomized Controlled Trial

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OBJECTIVE: Despite lack of efficacy data, the majority of first-trimester surgical abortions are performed with a paracervical block. Women may be unnecessarily exposed to a painful injection and potentially noxious medication. Our objective was to estimate the effect of a paracervical block and the effect of gestational age on patient pain perception.

METHODS: This was a randomized, single-blind trial of patients undergoing abortion receiving paracervical block or sham stratified by gestational age (early: less than 8 weeks of gestation, n=60; late: 8–10 6/7 weeks of gestation, n=60). Premedicated with ibuprofen and lorazepam, all participants received 2 mL 1% buffered lidocaine injected at the tenaculum site followed by a slow, deep injection of 18 mL at four sites (block) or no injection (sham) with a 3-minute wait. The primary outcome was dilation pain (100-mm visual analog scale). Secondary outcomes included pain at additional time points, satisfaction, need for more analgesics, and adverse events.

RESULTS: Full enrollment occurred (n=120). We used intent-to-treat analysis. Demographics did not differ between groups. Paracervical block administration was painful (mean 55 mm compared with sham 30 mm, $P<.001$) but decreased dilation pain (42 mm compared with 79 mm, $P<.001$) and aspiration pain (63mm compared with 89 mm, $P<.001$). These results were consistent for both gestational age strata; however, paracervical block benefit was greater at an earlier gestation. Satisfaction scores with pain control and the procedure were significantly higher in the block group.

CONCLUSION: Although paracervical block is painful, it reduces first-trimester abortion pain regardless of gestational age, but the benefit on dilation pain was greater at earlier gestations.

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Elective abortion is among the most common outpatient surgical procedures, with an estimated 42 million performed yearly worldwide, nearly 90% in the first trimester.[1,2]

Although paracervical block is routinely used for pain management in first-trimester surgical abortion,[3] a systematic review showed a lack of documented efficacy.[4] The majority of the existing literature includes no true sham arm. Only Kan et al[5] compared a paracervical block with no injection and observed no difference in pain. Kan et al's study design using conscious sedation and cervical ripening with misoprostol may have masked the effect of the paracervical block. Paracervical block administration has been painful for patients.[6,7] Morbidity and mortality from lidocaine toxicity, although rare, have been reported.[8–11] Therefore, the widespread use of a paracervi-

cal block, in the absence of robust evidence supporting its efficacy, may expose patients to a painful and potentially noxious injection with no benefit.

However, reviewing studies that compare active treatment arms, several potentially beneficial techniques include carbonated lidocaine,[12,13] deep injection to 3 cm,[12,14] a four-site injection,[6] slow injection (over 60 seconds),[13] and waiting 3 minutes between block and dilation.[15,16]

Gestational age may be a confounder regarding paracervical block efficacy. More pain would be expected with the increasing need for cervical dilation as gestational age advances. Prior studies have been conflicting.[17–19]

Our research goals were to estimate the efficacy of paracervical block on pain perception during first-trimester surgical abortion and examine the effect of gestational age on this perception. The hypotheses are that paracervical block changes the patient's pain perception at different steps during a first-trimester surgical abortion as compared with no paracervical block and that gestational age changes this effect.

MATERIALS AND METHODS

A randomized, single-blind, controlled trial was conducted at Planned Parenthood of the Columbia Willamette in Portland, Oregon, from April to October 2010. The institutional review board at Oregon Health & Science University and the Planned Parenthood Federation of America Research Department approved the study protocol.

After confirming their desire to proceed with an abortion, women requesting termination of pregnancy at less than 11 weeks of gestation by ultrasonography were recruited and before study participation signed an informed, written consent. Inclusion criteria included: age older than 18 years, good general health, and English-speaking or Spanish-speaking. Women were excluded if they did not meet inclusion criteria, requested intravenous sedation, which would have possibly blunted the effect of the paracervical block, or were unable or unwilling to receive ibuprofen, lorazepam, paracervical block, or all of these. Women with gestations of 11 weeks and above were specifically excluded because misoprostol cervical preparation is used at this clinic. Preprocedure counseling and evaluation were consistent with clinic protocols. Before their procedure, participants completed a demographics form and 100-mm visual analog scales on baseline pain, expected pain (anchors: 0 mm=no pain, 100 mm=worst pain in my life), and procedure-related and pain-related nervousness (anchors: 0 mm=not nervous, 100 mm=very nervous). All participants were premedicated with 800 mg oral ibuprofen and 2 mg oral lorazepam at least 30 minutes before the procedure.

Women were randomized to receive a paracervical block of 20 mL 1% buffered lidocaine or a sham (Table 1; Fig. 1). The paracervical block chosen for this study was based on a combination of techniques supported by the literature.[6,12–16] Randomization was computer-generated (block size six; generated by study staff not involved in enrollment of participants) and stratified by gestational age less than 8 weeks (early) or 8–10 6/7 weeks (late). Allocation concealment was ensured using sequentially numbered opaque, sealed envelopes, opened only after the patient was put in a room for her procedure.

All participants were counseled with a standardized script during the tenaculum and paracervical block (or sham) portion of the procedure in an effort to maintain blinding, eg, "You may or may not feel a sharp pinch…" After paracervical block or sham, a standardized wait of 3 minutes ensued before manual dilation of the cervix. Everyone in the room (woman, advocate, assistant) except for the surgeon was blinded to the technique. Experienced abortion providers performed all of the procedures in this study with either a manual (usually at less than 8 weeks) or electric (usually 8 weeks and more) vacuum aspiration device. Cannula size in millimeters generally corresponded to gestational age in weeks; a 6-mm cannula was the smallest size used.

Participants rated their pain using a visual analog scale (anchors 0 mm=no pain and 100 mm=worst pain in my life) at several time points (immediately on completion of each respective step): 1) speculum insertion; 2) administration of a paracervical block; 3) cervical dilation (primary outcome); 4) uterine suction aspiration; and 5) 30 minutes later in the recovery room. Thirty minutes postoperatively, women rated their satisfaction with pain control and their general experience (anchors 0 mm=not at all satisfied and 100 mm=very satisfied) and were asked which group they thought they had been randomized to. To provide independent answers, participants were unable to access their prior responses. The abortion provider was responsible for recording acute complications from the procedure. A data safety-monitoring committee was created to review any concerns regarding serious adverse events.

All analyses were performed according to intention-to-treat basis. Perioperative characteristics were examined among randomization groups using Fisher's exact test.

For the primary analysis, mean change during the procedure and mean difference in self-reported visual

Table 1. Paracervical Block Technique

Paracervical Block Group	Sham Paracervical Block Group
Syringe loaded with 18 mL of 1% lidocaine buffered with 2 mL 8.4% sodium bicarbonate (20 mL total); 20-gauge spinal needle	Syringe loaded with 18 mL of 1% lidocaine buffered with 2 mL 8.4% sodium bicarbonate (20 mL total); 20-gauge spinal needle
2 mL injected at the tenaculum site, 12 o'clock superficially into the cervix	2 mL injected at the tenaculum site, 12 o'clock superficially into the cervix
The tenaculum is immediately placed at 12 o'clock	The tenaculum is immediately placed at 12 o'clock
The remaining 18 mL are injected slowly over 60 sec into the cervicovaginal junction in four equal aliquots at 2, 4, 8, and 10 o'clock; the injection is continuous from superficial to deep (3 cm) to superficial (injecting with insertion and withdrawal)	Over 60 seconds, without moving the tenaculum, a capped needle gently touches the vaginal sidewall at the level of the external os at 4 and 8 o'clock
Dilation begins 3 min after application of the block	Dilation begins 3 min after application of the block

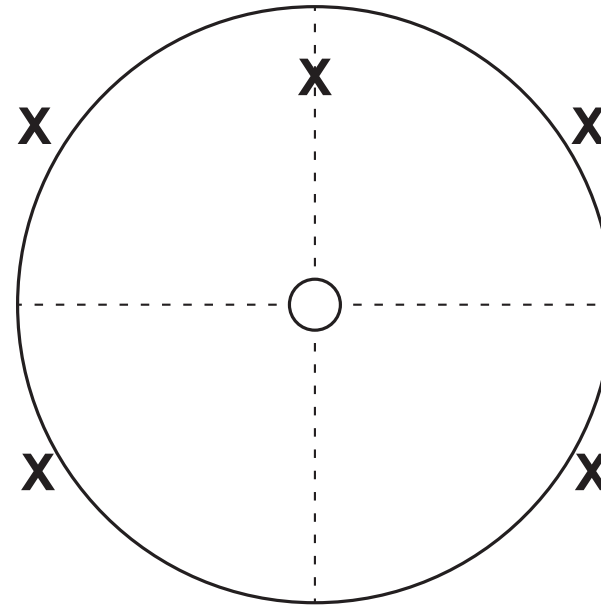

Fig. 1. Cervical tenaculum injection site (12 o'clock) and four paracervical (cervicovaginal junction) injection sites (2, 4, 8, and 10 o'clock).
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analog scale at each step during the procedure were compared between sham and paracervical block using a mixed-effects model a repeated-measures approach. Three patients in the sham group reported an unusually high level of pain (visual analog scale greater than 80 mm) at baseline; their raw data were included. To be consistent with common clinical reporting of visual analog scale results, we chose to present mean visual analog scale at each step. To determine whether gestational age was related to pain scores with dilation and aspiration in the two study groups, the correlation between gestational age and pain levels in each study group was evaluated using Pearson correlation coefficient. In addition, we compared both dilation and aspiration pain between early (less than 8 weeks) and late (8–10 6/7 weeks) gestational age groups (stratified during randomization) and between groups (sham and paracervical block) using a mixed model to account for heterogeneous variance between groups. Results of comparing pain levels between sham and paracervical block during the procedure and gestational age effect were verified using a generalized linear mixed model, which accommodates the nonnormal or skewed distribution over time or unequal variance among groups (SAS 9.2). Finally, patients' overall satisfaction (visual analog scale, anchors: 0 mm=not at all satisfied, 100 mm=very satisfied) with pain control and their experience were examined between groups using Wilcoxon's two-sample test. All analyses were performed using SAS software, two-sided *P* values were reported, and $P<.05$ was considered statistically significant.

Based on previous data, a 30% or 13-mm to 20-mm difference on a 100-mm pain visual analog scale has been considered clinically meaningful.[20–22] The mean of the standard deviation in previous studies was approximately 26 mm.[4] To detect a 15-mm or greater difference on a 100-mm visual analog scale with 80% power and a significance level of .05, a total of 98 participants (49 in sham or paracervical block) was required according to a two-sided two-sample *t* test. Adding 10% patients to compensate for possible withdrawal of patients from the study resulted in a total of 120 participants.

RESULTS

A total of 120 women were recruited between April and October 2010 with a 1:1 randomization to paracervical block or sham for each gestational age stratum; of these, 60 women were recruited for each gestational age stratum. Participant flow is depicted in Figure 2. One patient was inadvertently randomized to the late gestational age stratum when in fact she was early. The main reasons for study exclusion were a

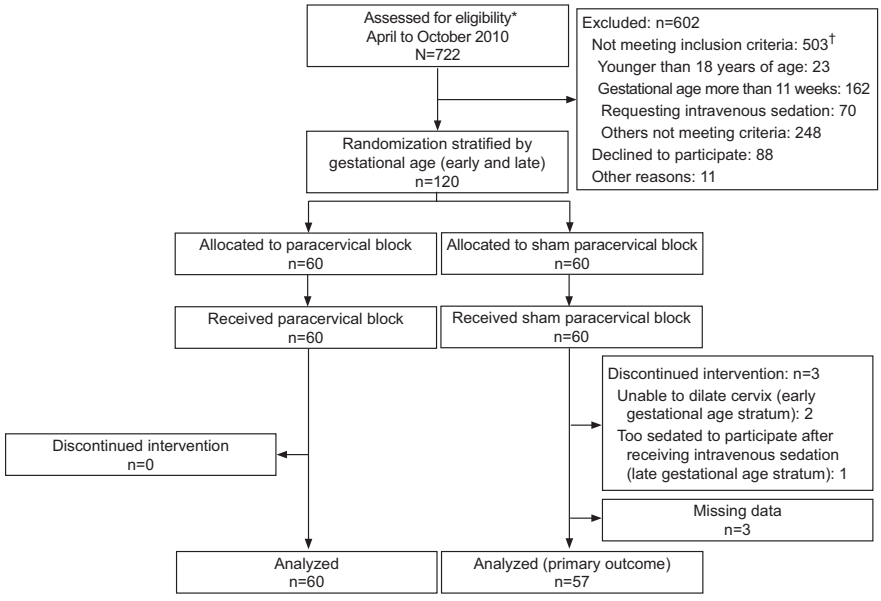

Fig. 2. Flow of participants. *After recruitment of the early gestational age stratum was complete, 88 women with early gestational age presented but were not approached (excluded). †Only the most common reasons for exclusion are listed.

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gestational age over 10 6/7 weeks or a desire for intravenous sedation. Recruitment for the early gestational age stratum was completed first; while continuing recruitment for the late gestational age stratum, 88 women with an early gestational age had to be excluded. Three women did not complete the study as a result of 1) the inability to dilate the cervix and complete the procedure (n=2, sham and early gestational age strata); and 2) request for intravenous pain medication during the procedure followed by the inability to complete the requisite visual analog scales as a result of to sedation (n=1, sham and late gestational age strata). Of note, the results remained unchanged when imputing 0 mm as the reported pain level for the latter patient.

Demographics stratified by gestational age are presented in Table 2 and were similar among groups. The majority of patients were white, with an average age of the mid-20s. The mean gestational age was 8 weeks for the entire study population, 6 2/7 weeks in the early gestational age stratum, and 9 2/7 weeks in the late stratum. Overall, the need for additional

Table 2. Demographic Characteristics

	Early Gestational Age Stratum		Late Gestational Age Stratum	
Characteristic	Sham Paracervical Block (n=30)	Paracervical Block (n=30)	Sham Paracervical Block (n=30)	Paracervical Block (n=30)
Patient age (y)	25.6±5.2	26.4±6.0	25.5±4.8	25.1±5.2
Gestational age (wk)	6.4±1.0	6.2±1.0	9.1±1.2	9.4±0.9
Race				
White	22 (75.9)	20 (69.0)	22 (73.3)	16 (53.3)
African American	0	1 (3.4)	3 (10.0)	3 (10.0)
Asian	3 (10.3)	2 (6.9)	0	0
More than one race or other	4 (13.3)	6 (20.0)	5 (16.7)	11 (36.7)
Nulliparity	18 (60.0)	19 (63.3)	12 (40.0)	17 (56.7)
Previous vaginal deliveries (yes or no)	10 (33.3)	7 (23.3)	14 (46.7)	8 (26.7)
Previous surgical abortions (yes or no)	9 (30.0)	10 (33.3)	9 (30.0)	8 (26.7)
Level of menstrual symptoms				
Easy or mild cramping	22 (73.3)	15 (50.0)	19 (63.3)	17 (56.7)
Requiring medication or unable to work	8 (26.7)	15 (50.0)	11 (36.7)	13 (43.3)
Body mass index (kg/m^2)	25.1±5.7	23.5±4.9	27.4±5.5	25.5±5.6

Data are mean±standard deviation or n (%). Percent totals may not add up to 100 because of rounding.

Table 3. Perioperative Variables

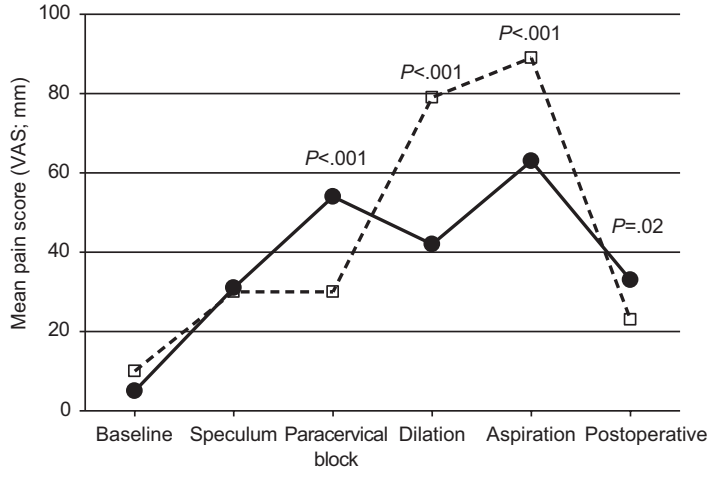
Variable	Early Gestational Age Stratum		Late Gestational Age Stratum	
	Sham Paracervical Block (n=30)	Paracervical Block (n=30)	Sham Paracervical Block (n=30)	Paracervical Block (n=30)
Analgesics				
Acetaminophen premedication (optional)	5 (16.7)	2 (6.7)	6 (20.0)	4 (13.3)
Intraoperative additional analgesics	0	0	1 (3.3)	0
Postoperative narcotics	0	3 (10.0)	0	10 (33.3)*
Complications				
Intraoperative (inability to dilate cervix)	2 (6.7)	0	0	0
Postoperative (reaspiration)	0	0	1 (3.3)	1 (3.3)

Data are n (%).
* P=.001 (Fisher's exact test).

analgesics was rare and not different between groups as were complications and adverse events (Table 3). No adverse events were medication-related.

Pain levels in visual analog scale between sham and paracervical block during the abortion procedure are illustrated in Figure 3. Baseline and speculum insertion pain did not differ between paracervical block and sham groups. Women receiving a paracervical block reported significantly less pain with both dilation (mean 42 compared with 79 mm, P<.001) and aspiration (mean 63 compared with 89 mm, P<.001) than women in the sham group but more pain with the actual administration of the paracervical block (mean 54 compared with 30 mm, P<.001). However, women receiving a paracervical block had slightly higher postoperative pain scores (mean 33 compared with 23 mm, P<.02) and requested more postoperative narcotics (Fig. 3; Table 3).

Figure 4 depicts the box plots of both dilation (Fig. 4A) and aspiration pain (Fig. 3B) between gestational age sham and paracervical block groups. Regardless of gestational age being early or late, dilation and aspiration pain scores were significantly lower in the paracervical block group. In the paracervical block group, the correlation between dilation pain and gestational age was significant (r=0.36, P=.005, data not shown). Dilation pain scores were significantly lower at early (median 32 mm, range 0–88 mm) than at late (median 57 mm, range 1–100 mm) gestational age (P=.02) (Fig. 4A), whereas aspiration pain was similar between early and late groups (Fig. 4B). In the sham group, no association was found for



	Mean (standard deviation)					
Sham paracervical block	10 (21)	30 (21)	30 (25)	79 (18)	89 (12)	23 (23)
Paracervical block	5 (9)	31 (25)	54 (27)	42 (29)	63 (27)	33 (25)

Fig. 3. Visual analog scale (VAS) pain scores during the procedure comparing paracervical block and sham treatment.

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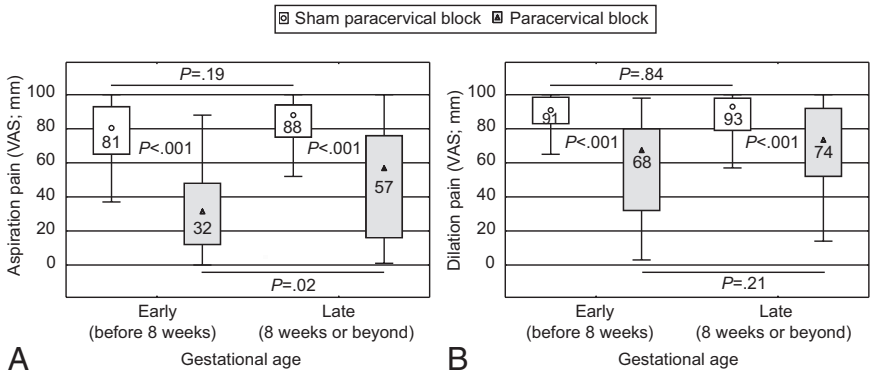

Fig. 4. Box plot of dilation **(A)** and aspiration **(B)** pain by gestational age.

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both dilation and aspiration with gestational age (r=0.10, P=.45, data not shown), and pain level was similar between early and late for both dilation (median 81 compared with 88 mm) and aspiration pain (median 91 compared with 93 mm).

Pain medication use in the past 60 days did not differ between groups and was not associated with dilation or aspiration pain.

Satisfaction scores, especially with pain control but also with the procedure, were significantly higher in paracervical block group (Fig. 5). Of note, the majority of women were able to identify to which group they had been randomized (sham 69% and paracervical block 70%).

DISCUSSION

This randomized trial demonstrated that paracervical block is effective in decreasing patient-reported pain at various steps throughout an induced abortion procedure. Although paracervical block administration was painful, it significantly decreased cervical dilation and uterine aspiration pain. Although paracervical block decreased pain regardless of gestational age, its effect on dilation pain appeared to wane with increasing gestational age.

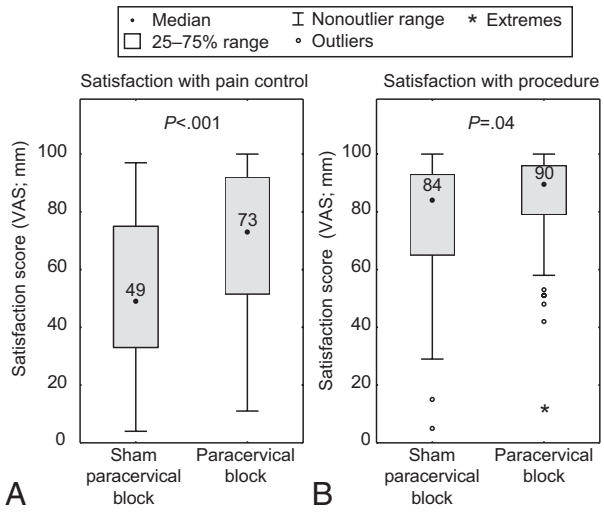

Fig. 5. Box plot of satisfaction with pain control **(A)** and procedure **(B)**.

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The strengths of the present study include its randomized single-blind controlled design with a separate randomization for early and late gestational age to ensure a representative distribution. We used a sham comparison arm in the absence of any confounders such as conscious sedation or cervical ripening. We encountered minimal dropout and intention-to-treat practices were used.

The generalizability of our data is limited because we only included women with a gestational age less than 11 weeks. This limit was purposefully chosen to reduce confounding because standard clinical protocols at our study site require cervical ripening with misoprostol after 10 6/7 weeks of gestational age. Because the benefits of paracervical block appear to decrease with increasing gestational age, further study is necessary to see if paracervical block use should be recommended above 11 weeks of gestation or in the presence of misoprostol for cervical ripening.

Unfortunately, most women in the study were able to identify the treatment group to which they were randomized, which may have introduced reporting bias. We believe this occurred from the very detailed description of the study procedures required of us to include in the written consent. Nonetheless, women still reported that paracervical block administration hurt and our effect size far exceeded what one would expect if only a "placebo" effect was being reported for the paracervical block.[23,24] A mean pain reduction of 13 mm or more measured on a 100-mm visual analog scale has been considered clinically

meaningful[20–22]; the effect size observed in our results was 20–30 mm.

Paracervical block is thought to provide pain control for cervical dilation through the parasympathetic fibers of S2 to S4 innervating cervix and lower uterine segment. Because the block does not reach the sympathetic fibers from T10 to L1 innervating the uterine fundus,[8] the mechanism of aspiration pain may not be explained by this anatomic distribution of nerves unless one assumes that the 3-minute wait allowed for the anesthetic to disseminate upward. However, this hypothesis is in conflict with the increased postoperative pain and request for more postoperative analgesics in the paracervical block group. Pain relief from lidocaine should persist for 1.5–2 hours; if greater distribution of the analgesic occurred, we would have expected the opposite in these women. However, even with the increase in postoperative pain, satisfaction was significantly higher in the paracervical block group. Our original hypothesis was that increasing pain occurs with increasing gestational age as a result of the increased need for dilation. The existing literature is conflicting whether earlier or later gestational age experiences more pain with observational data suggesting no correlation or increased pain at earlier gestational age. We found that dilation pain significantly increased with gestational age but only in the paracervical block group. Interestingly, this correlation was not present in our sham group, which may be the result of the overall increase in procedure-related pain for this group blunting the small gestational age-associated differences.

Not surprisingly, procedure-related pain was negatively correlated with pain-related and procedure-related satisfaction (data not shown). Satisfaction was significantly lower in the sham group, indicating that women find a painful paracervical block injection more acceptable than the pain experienced with the abortion procedure. However, overall satisfaction rates were high regardless of pain control, which highlights that analgesia is only one aspect of the abortion experience.

To ensure that our study would have the greatest chance of demonstrating an effect, we purposefully selected a rigorous paracervical block technique that requires more needle sticks (four rather than two), more local anesthetic (20 mL rather than 10 mL), and a longer wait time (3 minutes compared with no wait) than the technique used by most clinicians. Therefore, our results should not be considered generalizable to other paracervical block techniques. In fact, our technique likely resulted in the observed difference from studies that have not demonstrated a positive effect.[4] However, our results do not allow us to infer whether the anesthetic effect of a paracervical block is principally related to distribution (eg, number of needle sticks, volume), dose (eg, total drug delivery, concentration, drug pharmacokinetics), or set-up time (eg, delay between injection and procedure) of a local anesthetic.

In conclusion, our sham paracervical block controlled randomized controlled trial supports a benefit of the widely used paracervical block for induced first-trimester surgical abortion regardless of gestational age. Future research should focus on refinement of the paracervical block technique.

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